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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,577	08/29/2002	Glenn Dranoff	50059/005002	5254

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EXAMINER	
DAVIS, MINH TAM B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/762,577	DRANOFF ET AL.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-85* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *55 and 56* is/are allowed.

6)☒ Claim(s) *18-23,50-52 and 57-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election of Group H, claims 18-23, 50-52, 55-62, nucleic acid of SEQ ID NO:11, in the reply filed on 11/23/05 is acknowledged.

After review and reconsideration, the restriction requirement of 09/21/05 has been withdrawn and replaced with the following new restriction requirement, to include in group A, claims that were inadvertently omitted, and species requirement for groups A-D:

Election/Restriction

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group A, claim(s) 1-2, 5-15, 18-23, 30, 32-37, 50-52, 78-85, drawn to a method for identifying a nucleic acid encoding a tumor antigen, the TRAAM nucleic acid of SEQ ID NO:1, 3 and 17-19, and a method for diagnosing a tumor which is leukemia , comprising detecting the TRAAM nucleic acid .

Group B, claim(s) 1-2, 5-15, 30, 32-37, 78-85, drawn to a method for identifying a nucleic acid encoding a tumor antigen, the TRAAM nucleic acid of SEQ ID NO:1, 3 and 17-19, and a method for diagnosing a tumor which is not leukemia, comprising detecting the TRAAM nucleic acid .

A method detecting each of the following tumors constitutes a single invention: lymphoma, brain tumor, melanoma, fibrosarcoma, uterine, cervical, testicular, liver, ovarian, lung, renal cell, colon, breast, prostate or bladder carcinoma.

Group C, claim(s) 1-2, 5-15, 30, 32-37, drawn to a method for identifying a nucleic acid encoding a tumor antigen, which is the nucleci acid of SEQ ID NO: 7-9, 11, 14-16, or a method for diagnosing a tumor, comprising detecting said nucleic acid .

A method using each of the nucleic acids of SEQ ID NO:7-9, 11, 14-16, for detecting each of the following tumors constitutes a single invention: leukemia, lymphoma, brain tumor, melanoma, fibrosarcoma, uterine, cervical, testicular, liver, ovarian, lung, renal cell, colon, breast, prostate or bladder carcinoma.

Group D, claim(s) 3-4, 5-15, 26, 30-31, 36-37, drawn to a method for identifying a tumor antigen, encoded by SEQ ID NO: (1, 3, 17-19), 7-9, 11, 14-16, or a method for diagnosing tumor, comprising detecting the tumor antigen.

A method using each of polypeptide encoded by the nucleic acids of SEQ ID No: (1, 3,17-19), 7-9, 11, 14-16, for detecting each of the following tumors constitutes a single invention: leukemia, lymphoma, brain tumor, melanoma, fibrosarcoma, uterine, cervical, testicular, liver, ovarian, lung, renal cell, colon, breast, prostate or bladder carcinoma.

Group E, claims 14-15, 27, 29, 38, 48, drawn to a method for determining the level of an antibody or for detecting a tumor, comprising detecting an antibody that specifically binds to a tumor antigen, encoded by SEQ ID NO: (1, 3, 17-19), 7-9, 11, 14-16.

A method detecting an antibody to each of polypeptide encoded by the nucleic acids of SEQ ID No: (1, 3,17-19), 7-9, 11, 14-16, for detecting each of the following tumors constitutes a

single invention: leukemia, lymphoma, brain tumor, melanoma, fibrosarcoma, uterine, cervical, testicular, liver, ovarian, lung, renal cell, colon, breast, prostate or bladder carcinoma.

Group F, claims 14-15, 28-29, drawn to a method for detecting a tumor, comprising detecting a cytotoxic T lymphocyte specific for a tumor antigen, encoded by SEQ ID NO: (1, 3, 17-19), 7-9, 11, 14-16.

A method detecting for each tumor cited in claim 29, comprising detecting a CTL specific for each of polypeptide encoded by the nucleic acids of SEQ ID No: (1, 3,17-19), 7-9, 11, 14-16 constitutes a single invention.

Group G, claims 16-17, 49, 53-54, 74-77, drawn to a polypeptide encoded by SEQ ID NO: (1, 3, 17-19), 7-9, 11, 14-16.

Each polypeptide encoded by the nucleic acids of SEQ ID No: (1, 3,17), 7-9, 11, 14-16 constitutes a single invention.

Group H, claims 18-23, 50-52, 55-62, drawn to the nucleic acid of SEQ ID NO: 7-9, 11, 14-16, a probe, a vector and a cell comprising said nucleic acid.

Each nucleic acid of SEQ ID No: 7-9, 11, 14-16 constitutes a single invention.

Group I, claims 24-25, drawn to an antibody specific for a polypeptide encoded by SEQ ID NO: (1, 3, 17-19), 7-9, 11, 14-16.

An antibody specific for each polypeptide encoded by the nucleic acids of SEQ ID No: (1, 3,17-19), 7-9, 11, 14-16 constitutes a single invention.

Group J, claims 39-40, 67-70, drawn to a method for treating tumor, using a tumor antigen encoded by SEQ ID NO: (1, 3, 17-19), 7-9, 11, 14-16.

A method for treating each of the tumor consisting of leukemia, lymphoma, brain tumor, melanoma, fibrosarcoma, uterine, cervical, testicular, liver, ovarian, lung, renal cell, colon, breast, prostate or bladder carcinoma, using each of polypeptide encoded by the nucleic acids of SEQ ID No: (1, 3,17-19), 7-9, 11, 14-16 constitutes a single invention.

Group K, claims 39-40, drawn to a method for prophylaxis for a patient who is at risk for developing a tumor, using a tumor antigen encoded by SEQ ID NO: (1, 3, 17-19), 7-9, 11, 14-16.

A method for propholaxis of each of the tumor consisting of leukemia, lymphoma, brain tumor, melanoma, fibrosarcoma, uterine, cervical, testicular, liver, ovarian, lung, renal cell, colon, breast, prostate or bladder carcinoma, using each of polypeptide encoded by the nucleic acids of SEQ ID No: (1, 3,17-19), 7-9, 11, 14-16 constitutes a single invention.

Group L, claims 39, 41-45, drawn to a method for treating tumor, or stimulating apoptosis, using a nucleic acid of SEQ ID NO: (1, 3, 17-19).

A method for treating each of the tumor consisting of leukemia, lymphoma, brain tumor, melanoma, fibrosarcoma, uterine, cervical, testicular, liver, ovarian, lung, renal cell, colon, breast, prostate or bladder carcinoma, using the nucleic acids of SEQ ID No: (1, 3,17-19) constitutes a single invention.

Group M, claims 39, 41-45, 63-66, drawn to a method for treating tumor, or stimulating apoptosis, using a nucleic acid of SEQ ID NO: 7-9, 11, 14-16.

A method for treating each of the tumor consisting of leukemia, lymphoma, brain tumor, melanoma, fibrosarcoma, uterine, cervical, testicular, liver, ovarian, lung, renal cell, colon,

breast, prostate or bladder carcinoma, using each of the nucleic acids of SEQ ID No: 7-9, 11, 14-16 constitutes a single invention.

Group N, claims 39, 41-45, drawn to a method for prophylaxis for a patient who is at risk for developing a tumor, using a nucleic acid of SEQ ID NO: (1, 3, 17-19).

A method for propholaxis of each of the tumor consisting of leukemia, lymphoma, brain tumor, melanoma, fibrosarcoma, uterine, cervical, testicular, liver, ovarian, lung, renal cell, colon, breast, prostate or bladder carcinoma, using the nucleic acids of SEQ ID No: (1, 3,17-19) constitutes a single invention.

Group O, claims 39, 41-45, drawn to a method for prophylaxis for a patient who is at risk for developing a tumor, using a nucleic acid of SEQ ID NO: 7-9, 11, 14-16.

A method for propholaxis of each of the tumor consisting of leukemia, lymphoma, brain tumor, melanoma, fibrosarcoma, uterine, cervical, testicular, liver, ovarian, lung, renal cell, colon, breast, prostate or bladder carcinoma, using each of the nucleic acids of SEQ ID No: 7-9, 11, 14-16 constitutes a single invention.

Group P, claims 46-47, drawn to a method for treating a tumor, using an antibody specific for a tumor antigen, encoded by SEQ ID NO: (1, 3, 17-19), 7-9, 11, 14-16.

A method for treating each of the tumor consisting of leukemia, lymphoma, brain tumor, melanoma, fibrosarcoma, uterine, cervical, testicular, liver, ovarian, lung, renal cell, colon, breast, prostate or bladder carcinoma,using an antibody to each of polypeptide encoded by the nucleic acids of SEQ ID No: (1, 3,17-19), 7-9, 11, 14-16 constitutes a single invention.

Group Q, claims 71-73, drawn to a method for identifying a compound that modulates apoptosis or radiation sensitivity, comprising detecting the biological activity of MAIAP.

In addition, this application contains claims directed to the following patentably distinct species:

For groups A-C, the species of identifying a nucleic acid encoding a tumor antigen, using either an antibody or a cytotoxic T lymphocyte.

For group D, the species of identifying a nucleic acid encoding a tumor antigen, using either an antibody or a cytotoxic T lymphocyte.

The inventions are distinct, each from the other because of the following reasons:

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. When claims to different categories are present in the application, the claims will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) A product and a process specially adapted for the manufacture of said product; or (2) A product and a process of use of said product; or (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) A process and an apparatus or means specifically designed for carrying out the said process; or (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(b) and (d). Group I will be the main invention. After that, all other products and methods will be broken out as separate groups (see 37 CFR 1.475(d).)

Group A, claims 1-2, 5-15, 30, 32-37, 78-85, SEQ ID NO:1, 3, 17-19 forms a single general inventive concept.

Groups B, L, N are additional use of SEQ ID NO:1, 3, 17-19.

Groups C-F, J-K, M, O-Q do not share the same technical feature of group I, because the methods of groups C-F, J-K, M, O-Q do not use the sequences of SEQ ID NO:1, 3, 17-19 of group I.

Groups G-I do not share the same technical feature of group I, because the composition of groups G-I do not share a common structure with SEQ ID NO:1, 3, 17-19 of group I.

The species are distinct, because the antibody and the cytotoxix T lymphocytes do not share a common property, or characteristic.

Accordingly, Groups A-Q are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted.

If any one of groups A-D is elected, Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits, and a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

In a telephonic interview with TIMOTHY MURPHY on 04/25/06 Applicant elects Group H, claims 18-23, 50-52, 55-62, nucleic acid of SEQ ID NO:11.

A confirmation of this election is required in the response to this Office action.

Accordingly, Group H, claims 18-23, 50-52, 55-62, the nucleic acid SEQ ID NO:11, are examined in the instant application.

Claims 55-56 seem to be free of prior art and are allowable.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
1) It does not state that the person making the oath or declaration believes the named inventor or inventors to be the original and first inventor or inventors of the subject matter which is claimed and for which a patent is sought.

2) It does not state that the person making the oath or declaration has reviewed and understands the contents of the specification, including the claims, as amended by any amendment specifically referred to in the oath or declaration.
3) Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Continuation Data

If applicant desires priority under 35 U.S.C. 1 19(e), 120, 121 and 365(c) based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent applications (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. " should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

It is requested that applicant updates the status of all U.S. application numbers in the priority statement. See United States Patent and Trademark Office-OG Notices: 1268 OG 89 (18 -March 2003) "Benefit of Prior-Filed Application".

Information Disclosure Statement

The information disclosure statement filed 03/12/01 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the submission date of the information disclosure

statement is prior to the filing date, 08/29/2002 of the instant application. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Objections

1. Claims 18-23, 50-52 are objected to, because claims 18-23, 50-52 also contain non-elected inventions.

2. Claims 18-19, 21-23 are objected to, because claim 18 recites "MAIAP (SEQ ID NO:11)". It is not clear whether SEQ ID NO:11 is the MAIAP nucleic acid or is just one of the MAIAP nucleic acids.

This objection could be obviated by amending the claims, for example, to recite "the MAIAP SEQ ID NO:11".

3. Claims 20-21, 50-52, 57-62 are objected to for the use of the language "MAIAP" without being accompanied by a sequence identification number, as the sole means of identifying the claimed nucleic acid, because different laboratories may use the same laboratory designations to define completely distinct nucleic acids. Amendment of the claims to include physical and/or functional characteristics of "MAIAP", which unambiguously define "MAIAP" is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 23 is rejected under 35 USC 101 because the claim 23 is directed to non-statutory subject matter.

The cell as claimed has the same characteristics and utility as a cell found naturally and therefore do not constitute patentable subject matter. In the absence of the hand of man, the naturally occurring cell is considered non-statutory subject matter. Diamond v. Chakrabarty, 206 USPQ 193 (1980). Amendment of the claim to recite " an isolated cell" is suggested to overcome this rejection.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-21, 59, 60-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 20-21, 59, 60-62 indefinite because they recite "high stringent hybridization conditions".

The specification discloses that by "high stringent conditions" is meant conditions that allow hybridization "comparable" with the hybridization that occurs using a DNA probe of at

least 500 nucleotides in length, in a buffer containing 0.5M NaHPO4, pH 7.2, 7% SDS, 1mM EDTA, and 1% BSA at a temperature of 65^0 C, or a buffer containing 48% formamide, 4.8XSSC, 0.2M Tris-Cl, pH 7.6, 1X Denhardt's csolution, 10% dextran sulfate, and 0.1% SDS, at a temperature of 42^0 C (p.19, bridging p.20).

Due to the non-limiting language "comparable", and the lack of the wash conditions, the definition of "high stringent conditions" is not limiting.

Due to the non-limiting definition of "high stringent conditions", the specification does not provide a standard for ascertaining the requisite degree of high stringent conditions and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention and would not be able to determine the metes and bounds of the claims.

Claim Rejections - 35 USC § 112, Written description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-23, 50-52, 57-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 18-23, 50-52, 57-62 are drawn to:

1) A substantially pure nucleic acid comprising a sequence encoding a polypeptide "substantially identical" to a polypeptide encoded by MAIAP (SEQ ID NO:11) (claims 18-19).

2) A substantially pure nucleic acid comprising a probe, wherein said probe hybridizes under "high stringency conditions" to "MAIAP", wherein said probe "has" a nucleotide sequence "complementary" to at least 14 nucleotides of "MAIAP", a vector and a host cell comprising said nucleic acid (claims 20-23).

3) A vaccine for treatment of a tumor or prophylaxis against developing a tumor, comprising a nucleic acid encoding a tumor antigen, or a fragment thereof, wherein said fragment comprises at least 10 amino acids, wherein said tumor antigen is encoded by a nucleic acid encoded by "MAIAP" (claims 50-52).

4) A substantially pure nucleic acid that "comprises" at least 14, 16, 18, 22, 25, 50, 75 or 100 consecutive nucleotides, that display at least "85%, 90%, 92%, 95%, or 98% sequence identity" to a nucleotide sequence that is "complementary" to a nucleic acid that encodes "MAIAP", and wherein said nucleic acid hybridizes under high stringency conditions to a "MAIAP" nucleic acid (claims 57-59).

5) A substantially pure nucleic acid "comprising" at least 14, 14, 16, 18, 22, 25, 50, 75 or 100 consecutive nucleotides, wherein said nucleic acid hybridizes under high stringency conditions to a nucleic acid encoding "MAIAP", and wherein said nucleic acid is an antisense nucleic acid (claims 60-62).

The specification discloses that "substantially identical" is meant a polypeptide exhibiting at least 80%, 85%, 90% or 95% identity to a reference amino acid (p.21, lines 13-15). The specification further discloses that by "MAIAP polypeptide" is meant a polypeptide that is

substantially identical, as defined above, to SEQ ID NO:12. The specification however does not disclose which region of SEQ ID NO:11 confers the function of SEQ ID NO:11.

In view of the disclosure in the specification, claims 18-19, 21-23, as drawn to a sequence encoding a polypeptide "substantially identical" to a polypeptide encoded by SEQ ID NO:11, encompass variant MAIAP polypeptide having at least 80%, 85%, 90% or 95% identity to the polypeptide SEQ ID NO:12, encoded by the MAIAP nucleic acid SEQ ID NO:11, with unknown structure and function.

In addition, in view of the disclosure of the specification, "MAIAP" nucleic acid or polypeptide, without being accompanied by a sequence identification number, as claimed in claims 20-21, 50-52, 57-59, and 60-62, encompass variant MAIAP nucleic acid or polypeptide, having at least 80%, 85%, 90% or 95% identity to the MAIAP nucleic acid SEQ ID NO:11 or the MAIAP polypeptide SEQ ID NO:12, respectively, with unknown structure and function.

In addition, a complement could be a partial or a complete complement, wherein a partial complement could share with SEQ ID NO:11 or its fragment a few complementary nucleotides.

Further, due to the open language "a nucleic acid comprising a probe" of claim 20, and the language "said probe has" of claim 20, which language is reasonably interpreted as having the same meaning as the open language "comprising", the claimed probe could be of any size.

Thus, claims 20-21 encompass an unknown sequence attached to a fragment complementary to a 14 nucleotide fragment of SEQ ID NO:11, wherein said probe hybridizes to SEQ ID NO:11 via said common fragment with SEQ ID NO:11, under high stringency conditions.

Claims 57-59 encompass an unknown sequence with unknown structure having at least 14, 16, 18, 22, 25, 50, 75 or 100 consecutive nucleotides, wherein said unknown sequence has at least "85%, 90%, 92%, 95%, or 98% sequence identity" to an unknown nucleotide sequence that shares with SEQ ID NO:11 a few complementary nucleotides, and wherein said unknown sequence hybridizes under high stringency conditions to SEQ ID NO:11, via a common fragment with SEQ ID NO:11.

Claims 60-62 encompass an unknown sequence with unknown structure having at least 14, 14, 16, 18, 22, 25, 50, 75 or 100 consecutive nucleotides, wherein said unknown sequence hybridizes under high stringency conditions to SEQ ID NO:11 via a common fragment with SEQ ID NO:11.

The present claims encompass full-length genes and cDNAs that are not further described. There is substantial variability among the species of DNAs encompassed within the scope of the claims because the claimed nucleic acid is a fragment of any full-length gene or cDNA species. For example, a cDNA 's principle attribute would include its coding region. A partial cDNA that did not include a disclosure of any open reading frame (ORF) of which it would be a part, would not be representative of the genus of cDNAS because no information regarding the coding capacity of any cDNA molecule would be disclosed.

Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a]

written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." Id. At 1567, 43 USPQ2d at 1405. The court also stated that

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that □the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with

a known or disclosed correlation between function and structure, or some combination of such characteristics." Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to claims such as those at issue here.

Thus, the instant specification may provide an adequate written description of the claimed nucleic acid, as shown in the example of Lilly by structurally describing a representative number of nucleic acids, or by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, as shown in the example of Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not describe the claimed nucleic acid in a manner that satisfies either the standards as shown in the example of Lilly or Enzo. The specification does not provide sufficient structure or common structure, other than SEQ ID NO:11 encoding the polypeptide SEQ ID NO:12, to support the broad breath of the genus claimed. Nor is there any functional characteristics coupled with a known or disclosed correlation between structure and function. Although the specification discloses a single nucleic acid, SEQ ID NO:11, this does not provide a description of the claimed genus of nucleic acids that would satisfy the standard as shown in the example of Enzo.

The specification also fails to describe the claimed nucleic acid, by the standards shown in the example in Lilly. The specification describes only a single nucleic acid, SEQ ID NO:11. Therefore, it necessarily fails to describe a "representative number" of such species. In addition, the specification also does not describe "structural features common to the members of the genus, which features constitute a substantial portion of the genus."

In summary, in view of a lack of a disclosure of which region of SEQ ID NO:11 confers the function of SEQ ID NO:11, **there is no correlation between the structure of the claimed genus of nucleic acids and the function of SEQ ID NO:11.** Moreover, the disclosed single nucleic acid, **SEQ ID NO:11, is not a representative number for the claimed genus of nucleic acids.**

The specification does not provide an adequate written description of the claimed nucleic acid that is required to practice the claimed invention. Thus, the specification does not meet the 112, first paragraph written description requirement, and one of skill in the art would reasonably conclude that Applicant did not have possession of the claimed nucleic acid at the time the invention was made.

Claim Rejections - 35 USC § 112, Scope of Enablement

Claims 18-23, 50-52, 57-62 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:11, and an isolated host cell comprising SEQ ID NO:11, does not reasonably provide enablement for: 1) a MAIAP nucleic acid encoding a MAIAP polypeptide **"substantially identical"** to a polypeptide encoded by SEQ ID NO:11, 2) a MAIAP nucleic acid **"comprising"** a probe, wherein said probe hybridizes under high

stringency conditions to **"MAIAP"** and wherein said probe **"has"** a nucleotide sequence **"complementary"** to at least 14 nucleotides of MAIAP, 3) **"a vaccine"** for treatment of **"a tumor"** or prophylaxis against developing **"a tumor"**, comprising **"a MAIAP nucleic acid"** encoding a tumor antigen encoded by **"MAIAP"**, 4) a MAIAP nucleic acid that **"comprises"** at least 14, 16, 18, 22, 25, 50, 75 or 100 consecutive nucleotides, that display at least **"85%, 90%, 92%, 95%, or 98% sequence identity"** to a nucleotide sequence that is **"complementary"** to a nucleic acid that encodes **"MAIAP"**, and wherein said nucleic acid hybridizes under high stringency conditions to **"a MAIAP nucleic acid"**, 5) a MAIAP nucleic acid **"comprising"** at least 14, 14, 16, 18, 22, 25, 50, 75 or 100 consecutive nucleotides, wherein said nucleic acid hybridizes under high stringency conditions to a nucleic acid encoding **"MAIAP"**, and 6) **"a host cell"** comprising SEQ ID NO:18. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 18-23, 50-52, 57-62 are drawn to:

1) A substantially pure nucleic acid comprising a sequence encoding a polypeptide "substantially identical to a polypeptide encoded by MAIAP (SEQ ID NO:11) (claims 18-19).

2) A substantially pure nucleic acid comprising a probe, wherein said probe hybridizes under "high stringency conditions" to "MAIAP", wherein said probe "has" a nucleotide sequence "complementary" to at least 14 nucleotides of "MAIAP", a vector and a host cell comprising said nucleic acid (claims 20-23).

3) A vaccine for treatment of a tumor or prophylaxis against developing a tumor, comprising a nucleic acid encoding a tumor antigen, or a fragment thereof, wherein said

fragment comprises at least 10 amino acids, wherein said tumor antigen is encoded by a nucleic acid encoded by "MAIAP" (claims 50-52).

4) A substantially pure nucleic acid that "comprises" at least 14, 16, 18, 22, 25, 50, 75 or 100 consecutive nucleotides, that display at least "85%, 90%, 92%, 95%, or 98% sequence identity" to a nucleotide sequence that is "complementary" to a nucleic acid that encodes "MAIAP", and wherein said nucleic acid hybridizes under high stringency conditions to a "MAIAP" nucleic acid (claims 57-59).

5) A substantially pure nucleic acid "comprising" at least 14, 14, 16, 18, 22, 25, 50, 75 or 100 consecutive nucleotides, wherein said nucleic acid hybridizes under high stringency conditions to a nucleic acid encoding "MAIAP", and wherein said nucleic acid is an antisense nucleic acid (claims 60-62).

The following *Wands* factors have been considered when the 112, first paragraph, scope of enablement rejection was made.

The breadth of the claims

The breadth of the claims is broad.

In view of the disclosure in the specification, supra, claims 18-19, 21-23, as drawn to a sequence encoding a polypeptide "substantially identical" to a polypeptide encoded by SEQ ID NO:11, encompass variant MAIAP polypeptide having at least 80%, 85%, 90% or 95% identity to the polypeptide SEQ ID NO:12, encoded by the MAIAP nucleic acid SEQ ID NO:11, with unknown structure and function.

In addition, in view of the disclosure of the specification, supra, "MAIAP" nucleic acid or polypeptide, without being accompanied by a sequence identification number, as claimed in claims 20-21, 50-52, 57-59, and 60-62, encompass variant MAIAP nucleic acid or polypeptide, having at least 80%, 85%, 90% or 95% identity to the MAIAP nucleic acid SEQ ID NO:11 or the MAIAP polypeptide SEQ ID NO:12, respectively, with unknown structure and function.

Further, Claims 20-21 encompass an unknown sequence attached to a fragment complementary to a 14 nucleotide fragment of SEQ ID NO:11, wherein said probe hybridizes to SEQ ID NO:11 via said common fragment with SEQ ID NO:11, under high stringency conditions, supra.

Claim 23 encompasses a host cell comprising SEQ ID NO:11, obtained from gene therapy.

Claims 50-52 encompass a vaccine comprising a nucleic acid MAIAP encoding a tumor antigen, for use in gene therapy for treating or preventing any tumor, which is not necessarily cancerous, in view that a tumor encompasses any enlargement or abnormal growth, which is not necessarily cancerous, for example, cystic of the pancreas, splenic tumor or enlargement of the spleen, etc... (Stedman's medical dictionary, 25th ed, 1990, p.1652-1653).

Claims 57-59 encompass an unknown sequence with unknown structure having at least 14, 16, 18, 22, 25, 50, 75 or 100 consecutive nucleotides, wherein said unknown sequence has at least "85%, 90%, 92%, 95%, or 98% sequence identity" to an unknown nucleotide sequence that shares with SEQ ID NO:11 a few complementary nucleotides, and wherein said unknown sequence hybridizes under high stringency conditions to SEQ ID NO:11, via a common fragment with SEQ ID NO:11, supra.

Claims 60-62 encompass an unknown sequence with unknown structure having at least 14, 14, 16, 18, 22, 25, 50, 75 or 100 consecutive nucleotides, wherein said unknown sequence hybridizes under high stringency conditions to SEQ ID NO:11 via a common fragment with SEQ ID NO:11, supra.

The nature of the invention

The nature of the invention is complex. Although the specification discloses SEQ ID NO:11, the claims however encompass variants of SEQ ID NO:11, with unknown structure and function, in view a lack of a disclosure of which region of SEQ ID NO:11 confers the function of SEQ ID NO:11. Moreover, the claims encompass a host cell comprising SEQ ID NO:11, obtained from gene therapy, or a vaccine comprising a nucleic acid MAIAP encoding a tumor antigen, for use in gene therapy for treating or preventing a tumor, which is not necessarily cancerous.

The state of the prior art

Although the prior art teaches a sequence that comprises nucleotide 19 to nucleotide 1246 of SEQ ID NO:11 and would hybridize to SEQ ID NO:11 under high stringency (see 102 rejection below), the prior art does not teach SEQ ID NO:11, or gene therapy using SEQ ID NO:11 for treating or preventing any tumor.

The level of one of skill in the art

Although the level of skill in the field of molecular pathology is high, it would be undue experimentation for one of skill in the art to practice the claimed invention.

The level of predictability of the art

The level of unpredictability is high.

One could not predict what the function of the claimed nucleic acids is, and whether the claimed sequences would encode a protein having the function of the protein encoded by the full length sequence, SEQ ID NO:11, in view of teaching in the art that protein chemistry is unpredictable, which unpredictablility would apply as well to nucleic acids that encode proteins. Bowie et al (Science, 1990, 257:1306-1310) teach that an amino acid sequence encodes a message that determines the shape and function of a protein and that it is the ability of these proteins to fold into unique three-dimensional structures that allows them to function and carry out the instructions of the genome and further teaches that the problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex. (col 1, p. 1306). Bowie et al further teach that while it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of maintaining function are limited. Certain positions in the sequence are critical to the three dimensional structure/function relationship and these regions can tolerate only conservative substitutions or no substitutions (col 2, p. 1306). The sensitivity of proteins to alterations of even a single amino acid in a sequence are exemplified by Burgess et al (J of Cell Bio. 111:2129-2138, 1990) who teach that replacement of a single lysine reside at position 118 of acidic fibroblast growth factor by glutamic acid led to the substantial loss of heparin binding,

receptor binding and biological activity of the protein and by Lazar et al (Molecular and Cellular Biology, 1988, 8:1247-1252) who teach that in transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine or asparagine did not affect biological activity while replacement with serine or glutamic acid sharply reduced the biological activity of the mitogen. These references demonstrate that even a single amino acid substitution will often dramatically affect the biological activity and characteristics of a protein.

Further, one cannot predict that SEQ ID NO:11 could be used in gene therapy, for treating or preventing cancer, nor one can predict that a host cell containing SEQ ID NO:11 could be obtained from gene therapy. The state of the art at the time of filing was that the combination of vector, promoter, protein, cell, target tissue, level of expression and route of administration required to target the tissue of interest and obtain a therapeutic effect using gene therapy was unpredictable. For example, Miller (1995, FASEB J., Vol. 9, pages 190-199) review the types of vectors available for *in vivo* gene therapy, and conclude that "for the long-term success as well as the widespread applicability of human gene therapy, there will have to be advances...targeting strategies outlined in this review, which are currently only at the experimental level, will have to be translated into components of safe and highly efficient delivery systems" (page 198, column 1). Deonarain (1998, Expert Opin. Ther. Pat., Vol. 8, pages 53-69) indicate that one of the biggest problems hampering successful gene therapy is the "ability to target a gene to a significant population of cells and express it at adequate levels for a long enough period of time" (page 53, first paragraph). Deonarain reviews new techniques under experimentation in the art which show promise but states that such techniques are even less efficient than viral gene delivery (see page 65, first paragraph under Conclusion section). Verma

(Sept. 1997, Nature, Vol. 389, pages 239-242) reviews vectors known in the art for use in gene therapy and discusses problems associated with each type of vector. The teachings of Verma indicate a resolution to vector targeting has not been achieved in the art (see entire article). Verma also teaches appropriate regulatory elements may improve expression, but it is unpredictable what tissues such regulatory elements target (page 240, sentence bridging columns 2 and 3). Crystal (1995, Science, Vol. 270, page 404-410) also reviews vargene therapyious vectors known in the art and indicates that "among the design hurdles for all vectors are the need to increase the efficiency of gene transfer, to increase target specificity and to enable the transferred gene to be regulated" (page 409). Moreover, it is unpredictable that the claimed antisense could inhibit expression of SEQ ID NO:11 in vivo, in view of the unpredictability of antisense therapy. Branch, AD, 1998, TIBS 23: 45-50 teaches that it is very difficult to predict what portions of an RNA molecule will be accessible to an antisense sequence *in vivo*, and therefore, rational design of antisense molecule is not possible. Branch further teaches that although antisense oligonucleotides could be screened *in vitro*, it is not clear whether the identified antisense oligonucleotides are effective *in vivo*, and that *in vitro* studies will not always predict *in vivo* efficacy (p.49, first column, last paragraph, bridging second paragraph, and last column, second paragraph). In addition, Branch also teaches that although some antisense molecules had some clinical value through non-antisense effects, the non-antisense effects are not predictable and these effects must be explored on a case-by-case basis (p.50, first column). Further, even if an antisense oligonucleotide could be successfully used *in vitro* to inhibit the expression of a gene, it is unpredictable that said antisense oligonucleotide could be successfully used *in vivo*, because 1) successful application of antisense therapy *in vivo* has been

extremely limited, and that there are only a few reports of modulation of various pathological conditions by antisense therapy in rodents, and 2) even if the biological significant amounts of antisense molecules reach target cells, and bind to selected target sites on mRNA, a subsequent effect on regulation of translation is not guaranteed, as taught by Weiss, 1998, US 5,840,708. Gura (Science, 1995, 270:575-577) discloses, as drawn to antisense therapy, that the biggest concern is that antisense compounds simply don't work the way researchers once thought they did, i.e. the antisense oligonucleotides do not always work by true antisense mechanisms, and could be pharmaceutically effective via unexpected non-antisense side effects and have the same effects as non-specific, control oligonucleotides (page 576) . In addition, Gura teaches that other drawbacks shown in animal studies include difficulty getting antisense oligonucleotides to target tissues and the existence of potentially toxic side effects such as increased blood clotting and cardiovascular problems (page 575, col 1, para 2). In addition, Gura reports problems with synthetic antisense oligonucleotides in that unwanted and sometimes lethal side effects occurred in animal experiments, and that they block cell migration and adhesion to underlying tissue *in vitro* (page 576, col 3, para 1 and 3). Thus a high degree of unpredictability is associated with the use of antisense constructs employed in methods of inhibiting expression of a particular protein in an animal model and these problems would also be expected to be found in the human condition as contemplated by the specification.

Moreover, one cannot predict a successfull treatment of or preventing a tumor, wherein the tumor cells to be treated are not necessarily cancerous, and are unrelated to cancer, and thus having different etiology and characteristics, and would not predictably response to cancer therapy contemplated in the specification.

Working example, and the amount of direction provided by the inventor

The specification discloses the structure of the polynucleotide of SEQ ID NO:11. The specification discloses that sera of melanoma or lung cancer patients treated with autologous cancer cells has antibody reactivity against MAIAP polypeptide, higher than that of normal controls (p.32, last paragraph, bridging p.33, and figure 2).

The specification, however, does not disclose how to make and use the claimed numerous nucleic acid variants which are capable of functioning as that which is being disclosed, in view a lack of a disclosure of which region of SEQ ID NO:11 confers the function of SEQ ID NO:11. For example, Applicant has not taught what the structure is for the sequences attached to a complementary fragment SEQ ID NO:11, or what the coding regions are for these sequences, or what proteins are encoded by these sequences. In addition, although the specification discloses that the MAIAP polypeptide has the ability to inhibit apoptosis (p.24, lines 11-12, p.32), there were no data substantiating such disclosure, nor any example showing how to successfully use SEQ ID NO:11 for gene therapy for treating any tumor.

It is noted that MPEP 2164.03 teaches that "the amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability of the art. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The amount of guidance or direction refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature ot the invention, how to make, and how to use the invention, and

the more predictable the art is, the less information needs to explicitly stated in the specification. In constrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as how to make and use the invention in order to be enabling."

Given the above unpredictability, the lack of adequate disclosure in the specification, and in view of the complex nature of the claimed invention, and little is known in the art about the claimed invention, one of skill in the art would be forced into undue experimentation to practice the claimed invention.

Claim Rejections - 35 USC § 102 (e)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 20-23, 50-52, 57-62 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,472,172.

Claims 20-23, 50-52, 57-62 are drawn to:

1) A substantially pure nucleic acid comprising a probe, wherein said probe hybridizes under "high stringency conditions" to "MAIAP", wherein said probe "has" a nucleotide sequence "complementary" to at least 14 nucleotides of "MAIAP", a vector and a host cell comprising said nucleic acid (claims 20-23).

2) A vaccine for treatment of a tumor or prophylaxis against developing a tumor, comprising a nucleic acid encoding a tumor antigen, or a fragment thereof, wherein said fragment comprises at least 10 amino acids, wherein said tumor antigen is encoded by a nucleic acid encoded by "MAIAP" (claims 50-52).

3) A substantially pure nucleic acid that "comprises" at least 14, 16, 18, 22, 25, 50, 75 or 100 consecutive nucleotides, that display at least "85%, 90%, 92%, 95%, or 98% sequence identity" to a nucleotide sequence that is "complementary" to a nucleic acid that encodes "MAIAP", and wherein said nucleic acid hybridizes under high stringency conditions to a "MAIAP" nucleic acid (claims 57-59).

4) A substantially pure nucleic acid "comprising" at least 14, 14, 16, 18, 22, 25, 50, 75 or 100 consecutive nucleotides, wherein said nucleic acid hybridizes under high stringency conditions to a nucleic acid encoding "MAIAP", and wherein said nucleic acid is an antisense nucleic acid (claims 60-62).

Claims 50-52 recite the claimed nucleic acid, formulated as a vaccine composition for treatment of a tumor or prophylaxis against developing a tumor. However, this limitation is viewed as a recitation of intended use and therefore is not given patentable weight in comparing the claims with the prior art. Claims 50-52 read on the ingredient per se, which is a nucleic acid

encoding a tumor antigen, or a fragment thereof, wherein said fragment comprises at least 10 amino acids, wherein said tumor antigen is encoded by a nucleic acid encoded by "MAIAP".

A nucleic acid "comprising" a probe that hybridizes under high stringency conditions to MAIAP, wherein said probe "has" a nucleotide sequence complementary to at least 14 nucleotides of "MAIAP" encompasses an unknown sequence attached to a fragment complementary to a 14 nucleotide fragment of SEQ ID NO:11, wherein said probe hybridizes to SEQ ID NO:11 via said common fragment with SEQ ID NO:11, under high stringency conditions,supra.

A nucleic acid that "comprises" at least 14, 16, 18, 22, 25, 50, 75 or 100 consecutive nucleotides, that display at least "85%, 90%, 92%, 95%, or 98% sequence identity" to a nucleotide sequence that is "complementary" to a nucleic acid that encodes "MAIAP", and wherein said nucleic acid hybridizes under high stringency conditions to a MAIAP nucleic acid encompasses an unknown sequence with unknown structure having at least 14, 16, 18, 22, 25, 50, 75 or 100 consecutive nucleotides, wherein said unknown sequence has at least "85%, 90%, 92%, 95%, or 98% sequence identity" to an unknown nucleotide sequence that shares with SEQ ID NO:11 a few complementary nucleotides, and wherein said unknown sequence hybridizes under high stringency conditions to SEQ ID NO:11, via a common fragment with SEQ ID NO:11, supra.

A nucleic acid "comprising" at least 14, 14, 16, 18, 22, 25, 50, 75 or 100 consecutive nucleotides, wherein said nucleic acid hybridizes under high stringency conditions to a nucleic acid encoding MAIAP encompasses an unknown sequence with unknown structure having at least 14, 14, 16, 18, 22, 25, 50, 75 or 100 consecutive nucleotides, wherein said unknown

sequence hybridizes under high stringency conditions to SEQ ID NO:11 via a common fragment with SEQ ID NO:11, supra.

US 6,472,172 teaches the polynucleotide SEQ ID NO:1, an inhibitor of apoptosis (abstract, columns 11-13), a vector and host cell comprising said polynucleotide (column 17).

Under MPSRCH sequence similarity search, SEQ ID NO:1 of 1337 nucleotides in length taught by US 6,472,172 is 95% similar to most of the claimed SEQ ID NO:11, from nucleotide 19 to nucleotide 1246 of SEQ ID NO:11 (see MPSRCH search report, 2006, us-09-762-577b-11.rni, pages 2-3).

Further, the amino acid sequence encoded by SEQ ID NO:1 taught by the art is 98% similar to the polypeptide SEQ ID NO:12 encoded by the claimed polynucleotide SEQ ID NO:11, from amino acid 1 to amino acid 309 of SEQ ID NO:12 (MPSRCH search report, 2006, us-09-762-577b-12.p2n.rni, pages 2-3).

In view of the extensive homology, the polynucleotide SEQ ID NO:1 taught by the art would hybridize to the claimed SEQ ID NO:11 under high stringency conditions.

Further, one would readily envision the antisense sequence of SEQ ID NO:1 taught by the art.

All the limitations are met.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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MINH TAM DAVIS

April 20, 2006

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER